

# Notice of Allowability

Application No.

09/528,742

Examiner

Joseph T. Woitach

Applicant(s)

ROBEN ET AL.

Art Unit

1632

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to July 20, 2004.
2. ☒ The allowed claim(s) is/are 1-10, 13, 16, 19-32, 36, 39-46, 49, 51, 56-63.
3. ☒ The drawings filed on 20 March 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

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### **DETAILED ACTION**

This application filed March 20, 2000, claims benefit to provisional application 60/139,579, filed June 17, 1999.

Applicants' amendment, filed July 20, 2004, has been received and entered. The specification has been amended. Claims 11, 12, 14, 15, 17, 18, 33-35, 37, 38, 47, 48, 50, 52-55 have been canceled. Claims 1, 2, 19, 20, 21, 27, 30, 40, 43-46, 49, 51, 56 and 57 have been amended. Claims 1-10, 13, 16, 19-30, 32, 36, 39-46, 49, 51 and 56-63 are pending.

### ***Election/Restriction***

As noted in the previous office action the election of species of a specific (a) labeling domain and (b) specific binding domain was withdrawn. Further since there are only five different types of bonds now recited and encompassed by the claims (for example in (a)(iii)) it was indicated that it would not be an undue burden to examine each of these in the instant action. The elected species was withdrawn and all of the recited cleavable moiety with dithiopropionate was rejoined.

### ***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

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Authorization for this examiner's amendment was given in a telephone interview with Maya Skubatch on September 30, 2004.

The application has been amended as follows:

Amend claim 63 to read:

T[t]he method of claim 62 [52] wherein the organ-specific or tissue-specific protein is detected in only one tissue.

*Reasons for Allowance*

The following is an examiner's statement of reasons for allowance:

The amendment to the claims has obviated the specific basis of the rejections made under 35 USC 112, second paragraph. The claims were free of the art of record because while binding studies in vitro and in vivo were known at the time of filing, the specification and the method as claimed is drawn to specifically identifying proteins present on the luminal surface of a cell by using very mild conditions to obtain a very specific identification signal. It is conventional in the art to use more stringent conditions to obtain a more specific signal. The present specification demonstrates that these stringent conditions may increase the non-specific labeling and identification of proteins. Unexpectedly, the specification demonstrates that milder washing conditions, those that do not denature the protein, provide a more specific identification method for luminal proteins.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571)272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571)272-0532.

Joseph T. Woitach

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Joe Woitach